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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/702,189

11/05/2003

William G. Dennis

MPD-002.01

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03/11/2009

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EXAMINER

NGUYEN, TUAN VAN

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

03/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/702,189	Applicant(s) DENNIS, WILLIAM G.	
	Examiner TUAN V. NGUYEN	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 60-70 is/are pending in the application.
- 4a) Of the above claim(s) 16-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-14 and 62-70 is/are rejected.
- 7) ☒ Claim(s) 2,15 and 60-61 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In previous Office action, claims 1-15 and 60-70 were pending and they were examined and rejected.

Reopening of Prosecution After Appeal

2. In view of the appeal brief filed on December 8, 2008, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below:

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3731

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1, 62 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over by Watkin (US 3,797,076).**
5. Watkin discloses (see Figs. 1 and 2) a spring clip comprising, an upper arm or upper single element 12; a lower arm 14 or lower single element; a spring portion; the occlusion portion and the spring portion each having a wire width that no wider than the wire width in the direction that perpendicular to the occlusion member plane; and a lip or a guide portion 18 extending from the distal upper arm 12 and a lip or a guide portion 20 extending from the distal lower arm 14 wherein the guide portion is wider than the width of arms 12 and 14 (see col. 3, lines 28-42).
6. As to claim 1, the limitation of "the occlusion portion and the spring portion are formed from wire" is product by process claim. here it is noted that a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S. P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15, see footnote 3. Noting that the clip as disclosed by Watkin is made from plastic material. Examiner contends that there are plastic

materials that has mechanical properties that equivalent or better than some metal alloy. Extrinsic evidence, Davis et al. (US 6,241,740) the clip can be made from plastic or metal (col. 13, lines 53-58).

7. As to claim 63, see examiner response to applicant argument below.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. **Claims 5, 6, 7, 8, 9, 11, 12, 14, 63 and 68-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watkin (US 3,797,076)**

11. Referring to **claims 5, 6, 8, 9 and 11-12**, Watkin discloses the invention substantially as claimed except for the wire has a diameter in a range from about

10 mils to about 50 mils. It would have been obvious to one of ordinary skill in the art to make the clip from a wire having a diameter in the range as claimed by the applicant, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

12. Referring to **claims 7, 14 and 64**, Watkin discloses the invention substantially as claimed except for specifically discloses the spring biases the upper and lower single occlusion members to exert a maximum occluding force of about 0.20 pounds. Since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. It would have been obvious to one of ordinary skill in the art to design the clip as disclosed by Watkin to have a spring force of about 0.20 pounds of compressive force as claimed by the applicant.
13. Referring to **claims 68-70**, Watkin fails to disclose the material is titanium alloy comprises Ti-6Al-4V ELI. However, titanium alloy such as Ti-6Al-4V ELI is old and well known in the art. Extrinsic evidence, Murley et al (US 4,775,426) discloses surgical titanium alloy such as Ti-6Al-4V ELI (see Background of The Invention). It would have been obvious to one of ordinary skill in the art to further utilize the clip of Watkin into the art of medical device by manufacturing the clip from titanium alloy comprises Ti-6Al-4V ELI because titanium alloy has excellent

mechanical properties, biocompatible with human body, and also exhibits radiopacity property.

14. **Claims 1-14, 62 and 63-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen et al. (U.S. 3,193,732) in view Watkin (US 3,797,076).**
15. Referring to claims **1-6, 8-13, 60-62 and 63-68**, Frantzen discloses (see Figs. 6A-6C; col. 8, lines 28-40; and col. 14, lines 28-37) an occlusion clip comprising: made from a single wire includes an upper single element 305; a lower single element 310; a occlusion member plane defined by upper and lower single elements; and a spring portion 315 connecting the proximal upper member end to the proximal lower member, the spring portion having a interior spring height dimension in the occlusion member plane being less than twice the wire diameter and a maximum occlusion width dimension perpendicular to the occlusion member plane that is no greater than the wire diameter and the spring height dimension increases as a rotational separation between the single element upper occlusion member and the single element lower occlusion member increases. Figure 6B discloses the spring portion 315 defines a width dimension perpendicular to the occlusion member plane that is no greater than the wire height. Frantzen also discloses may be made of any suitable medical grade material including titanium super-elastic metals (see col. 8, lines 35-40). Frantzen discloses the invention substantially as claimed except for a guide portion extending from the distal upper

member end and a guide portion extending from the distal lower member end wherein the guide portion is wider than the wire width.

16. However, Watkin discloses such a feature. Watkin discloses (see Figs. 1 and 2) a spring clip comprising, among other things, a lip or a guide portion 18 extending from the distal upper arm 12 and a lip or a guide portion 20 extending from the distal lower arm 14 wherein the guide portion is wider than the width of arms 12 and 14 (see col. 3, lines 28-42). Apparently the design intended of the guide portions is so that the lips enable the clip to claim over any article (see col. 2, lines 29-32). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the lips as disclosed by Watkin into the clip of Frantzen so that it too would have the same advantage.
17. Referring to **claims 5, 6, 8, 9 and 11-12**, Frantzen discloses the invention substantially as claimed except for the wire has a diameter in a range from about 10 mils to about 50 mils. Noting that Frantzen discloses the shape and features of the surgical clip can be produced according to surgical procedure (see col. 13, lines 44-56). It would have been obvious to one of ordinary skill in the art to made the clip from a wire having a diameter in the range as claimed by the applicant, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Extrinsic evidence, Schmidt et al (U.S. 5,053,045) discloses a surgical clip that formed a single wire wherein the wire is

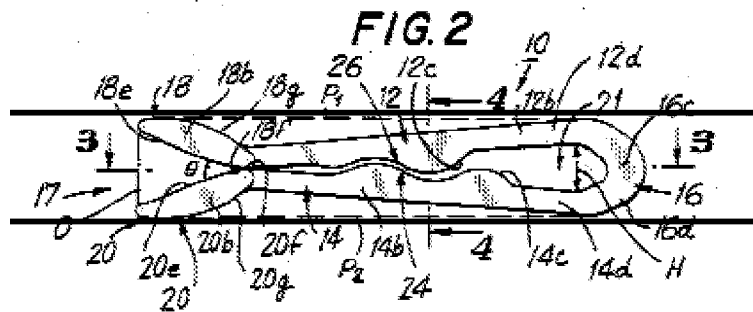
formed from titanium and has a diameter of 37 mils or 40 mils (see col. 4, lines 65 to col. 5, line 29).

18. Referring to **claims 7, 14 and 64**, Frantzen discloses the invention substantially as claimed except for specifically discloses the spring biases the upper and lower single occlusion members to exert a maximum occluding force of about 0.20 pounds. Since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. It would have been obvious to one of ordinary skill in the art to design the surgical clip as disclosed by Frantzen to have a spring force of about 0.20 pounds of compressive force as claimed by the applicant. Extrinsic evidence, Schmidt et al (U.S. 5,053,045) discloses a surgical clip wherein the clip has a spring force applied to the upper and lower single occlusion members to of about 200 grams or 0.20 pound (col. 8, lines 4-8).
19. Referring to **claims 69 and 70**, in previous Office Action, mailed out on 2/25/08, Examiner takes official notice in making a rejection of claims 69 and 70. Nowhere in the applicant arguments in an appeal brief filed on 12/8/08 indicates that applicant traverses the examiner's assertion of official notice. Therefore, the statement is taken to be admitted prior art because applicant failed to traverse the examiner's assertion of official notice.

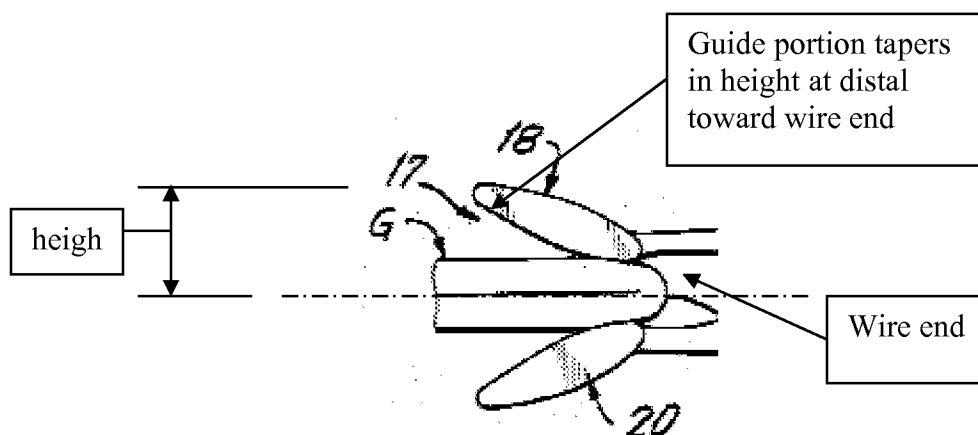
Response to Amendment

20. Applicant's arguments filed on December 8, 2008 with respect to rejection of claims 1-14, 62 and 64-70 under 35 USC § 103 have been fully considered but they are not persuasive.

- a. Applicant argues that Frantzen's clip and clip applier are best shown in Figs. 19A-B is incorrect. Frantzen's clip as shown in Figure 6A-6C was used in previous rejection and the clip does not required the clip applier as shown in Figure 19B. Noting that the clip and clip applier as shown in Figures 19A-B were not used in the rejection.
- b. Applicant argues that the clip as shown in Figs 19A if modified to incorporate the clip guide as taught by Watkin would cause the lips, especially the proximal end, be free to jiggle and jamming into the lumen wall of the clip applier is incorrect. Frantzen discloses (Figures 19A and 19B) the proximal end of the clip includes a notch 592 mating with the distal portion of the adjacent clip to stabilize the clip in both directions, especially, in the direction that shown in Figure 19B (col. 17, lines 10-14). Further, Figure 2 of Watkin's drawings (reproduced below) show the width of proximal end substantially equal the width of the distal end. Thus, incorporation of the guide members as taught by Watkin into the distal portion of Frantzen will stabilize the clip in the direction corresponding to the height of the clip as shown below.



21. With respect to applicant argument to the rejection of claims 2 and 15, applicant argues that the Frantzen as modified by Watkin fails to disclose the second planar of the clip guide being parallel to the first planar member of the clip guide has been fully considered and they are persuasive.
22. Applicant's arguments with respect to the rejection of claim 63 have been fully considered but they are not persuasive. Figures 2 and 5 (reproduced below) of Watkin's drawings show each clip guide portion tapers in height distally toward the respective first or second wire end.



Allowable Subject Matter

23. Claim 2, 15 and 60-61 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
3/10/09